IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

ROBERTA D. DAVIS, Plaintiff, vs. L'OREAL USA, INC.; L'OREAL USA PRODUCTS, INC.; and SOFTSHEEN-CARSON LLC, Defendants.	)	Civil Action No.: 3:23-292-MDL **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Roberta D. Davis, by and through the undersigned, makes the following Complaint against Defendant L'Oreal USA, Inc., L'Oreal USA Products, Inc., and SoftSheen-Carson LLC (hereinafter, collectively, "Defendants" or "L'Oreal") and alleges as follows:

NATURE OF THE ACTION

1. This action arises out of Roberta Davis's diagnosis of endometrial (uterine) cancer. Ms. Davis's endometrial cancer was directly and proximately caused by her regular and prolonged exposure to toxic endocrine disrupting chemicals ("EDCs"), such as phthalates, found in Defendants' Hair Straightening and/or Relaxing products.

2. Plaintiff brings this action against Defendants for claims arising from the direct and proximate result of Defendants, their directors, agents, heirs and assigns, and/or their corporate predecessors' negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of hair relaxing and/or straightening products, including but not limited to Dark &

Lovely Hair Relaxer (hereinafter, the "Product").

JURISDICTION AND VENUE

3. This Court has subject-matter jurisdiction over this case pursuant to 28 U.S.C. § 1332(a), because the amount in controversy exceeds $75,000, and Plaintiff and Defendants are residents of different states.

4. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts with the State of South Carolina and regularly conducted (and still conducts) business in the State of South Carolina relating to the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale Product, such that exercising jurisdiction over Defendants would not offend due process or traditional notions of fair play and substantial justice.

5. Defendants' Products were all sold either directly or indirectly to members of the general public within the State of South Carolina.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(a) and (b)(2) and 1391(c)(2) because a substantial part of the events or omissions giving rise to the claims occurred in this judicial district, and the Defendants are subject to this Court's personal jurisdiction. Venue is also proper under 18 U.S.C. § 1965 (a) because Defendants transact substantial business in this district.

7. Upon information and belief, at all relevant times, Defendants were present and transacted, solicited, and conducted business in the State of South Carolina through their employees, agents, and/or sales representatives and derived substantial revenue from such business.

8. At all relevant times, Defendants expected or should have expected that their acts

and omissions would have consequences within the United States and the State of South Carolina.

THE PARTIES

9. Plaintiff is and at all times relevant to this action was a citizen and resident of the State of South Carolina with her place of residence being Columbia, Richland County, South Carolina.

10. As a direct and proximate result of Ms. Davis using Defendants' Product and being exposed to the toxic chemicals contained within it, on or about March 18, 2021, she was diagnosed with endometrial adenocarcinoma (endometrial/uterine cancer) and underwent a total hysterectomy and bilateral salpingo-oophorectomy on March 30, 2021.

11. Defendant L'Oreal USA, Inc. is a corporation organized and existing under the laws of the state of Delaware, which maintains its principal place of business at 10 Hudson Yards, 347 10th Ave, New York, NY 10001, and process may be served upon its registered agent, Corporation Service Company, 80 State Street, Albany, New York 12207. L'Oreal USA, Inc. is a wholly-owned subsidiary of L'Oreal S.A. and manufactures, markets, advertises, labels, distributes, and sells the Toxic Hair-Straighteners and/or Relaxers at issue in this litigation.

12. Defendant L'Oreal USA Products, Inc. is a corporation organized and existing under the laws of the state of Delaware, which maintains its principal place of business at 10 Hudson Yards, 347 10th Ave, New York, NY 10001, and process may be served upon its registered agent, Corporation Service Company, 80 State Street, Albany, New York 12207. L'Oreal USA Products, Inc. is a wholly-owned subsidiary of L'Oreal USA, Inc. and manufactures, markets, advertises, labels, distributes, and sells the Toxic Hair-Straighteners and/or Relaxers at issue in this litigation.

13. Defendant Softsheen-Carson LLC is, and at all times relevant to this action was, a

New York Limited Liability Company with its principal place of business located at 10 Hudson Yards, 347 10th Avenue, New York, New York 10001, and process may be served upon its registered agent, Corporation Service Company, 80 State Street, Albany, New York 12207. Softsheen-Carson LLC's sole member is L'Oreal USA, Inc.

FACTUAL ALLEGATIONS

A. Hair Straighteners and Relaxers

14. Hair straighteners and/or relaxers, typically creams, lotions, and/or oils, are marketed to women to make their hair smoother, straighter, and easier to manage on a daily basis.

15. Hair relaxing, or lanthionization, can be performed by a professional cosmetologist in a salon or barbershop, or at home with at-home relaxer kits designed for individual use. These home kits are sold in grocery, drug, and beauty supply stores in cities throughout the United States.

16. Relaxers are applied to the base of the hair shaft and left in place for a "cooking" interval, during which the relaxer alters the hair's texture by purposefully damaging the hair's natural protein structure. The effect of this protein damage straightens and smooths the hair. After a period of weeks (4 – 8 weeks on average), depending on the hair's natural growth rate, the treated portion of the hair grows away from the scalp as new growth sprouts from the roots, requiring additional relaxer treatment to smooth the roots. These additional treatments are colloquially referred to in the community as "re-touches", resulting in women relaxing their new growth every four to eight weeks on average, usually for decades.

17. The toxic chemicals in hair relaxers are absorbed and metabolized through direct skin contact. Moreover, hair relaxers can, and often do, cause burns and lesions in the scalp, further facilitating entry of hair relaxer constituents into the body. The main ingredient of "lye" relaxers is sodium hydroxide; no-lye relaxers contain calcium hydroxide and guanidine carbonate,

and "thio" relaxers contain thioglycolic acid salts. No-lye relaxers are advertised to cause fewer scalp lesions and burns than lye relaxers, but there is little evidence to support this claim.

18. In some studies, up to 90% of black and brown women have used hair relaxants and straighteners, which is more commonplace for these women than for any other race.

19. Hair products such as relaxers contain hormonally active and carcinogenic compounds, such as phthalates, known to cause endocrine disruption, are not listed separately as ingredients but, instead, are often broadly lumped into the "fragrance" or "perfume" categories.

20. Relaxer habits usually begin in formative childhood years, and adolescence is likely a period of enhanced susceptibility to debilitating conditions resulting from exposure to these chemicals.[1]

21. In the 1990s, the first relaxer product for young Black girls, Just for Me ™, hit the market with a catchy advertising jingle that captured consumer attention.[2] It soon became one of the most popular straightening treatments, touting a no-lye formula designed to be gentler for children's sensitive scalps.

22. Once relaxer use begins in childhood, it usually becomes a lifetime habit. The duration and frequency of use of these products increases the risk of permanent and debilitating diseases associated with long-term exposure to endocrine-disrupting chemicals.

B. Regulatory Framework

23. The law does not require cosmetic products and ingredients, other than color additives, to have FDA approval before they go to market. But there are laws and regulations that apply to cosmetics placed into the market. The two most important laws pertaining to cosmetics

[1] Patrick Obukowcho, Hair Relaxers: Science, Design, and Application 27 (2018).
[2] Dana Oliver, The '90s Just For Me Hair Relaxer Commercial Song Is Stuck In Our Heads, HuffPost, Feb., 1, 2014. https://www.huffpost.com/entry/just-for-me-hair-relaxer-commercial-song_n_4689981 (last visited Oct. 27, 2022).

marketed in the United States is the Federal Food Drug and Cosmetic Ace ("FD&C Act") and the Fair Packaging and Labeling Act ("FPLA").

24. The FD&C Act expressly prohibits the marketing of "adulterated" or "misbranded" cosmetics in interstate commerce.

25. Adulteration refers to a violation involving product composition whether it results from ingredients, contaminants, processing, packaging shipping or handling.

26. Under the FD&C Act a cosmetic is adulterated if: 1) it bears or contains any poisonous or deleterious substance causing injury to the product user and 2) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

27. Misbranding refers to violations involving improperly labeled or deceptively packaged products.

28. Under the FD&C Act, a cosmetic is misbranded if 1) labeling is false or misleading, 2) the label does not include all required information, 3) required information is not prominent and conspicuous, 4) the packaging and labeling is in violation of an applicable regulation issued pursuant to section 3 and 4 of the Poison Prevention Packaging Act of 1970.[3]

29. Under U.S. law, cosmetic manufacturers are not required to submit their safety data to the FDA. However, it is against the law to put an ingredient in a cosmetic that makes the cosmetic harmful when used as intended.[4] An example is methylene chloride because it causes cancer in animals and is likely to be harmful to human health, too.[5]

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[3] Food and Drug Administration Cosmetic Act § 602 (1938).
[4] *Prohibited & Restricted Ingredients in Cosmetics*, U.S. Food and Drug Administration, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics (last visited Oct. 27, 2022).
[5] 21 Code of Federal Regulations § 700.19.

30. On May 19, 2022, the FDA issued a rule to amend its food additive regulations to no longer provide for most previously-authorized phthalates to be used as food additives because these uses have been abandoned by industry.[6] The FDA revoked authorizations for the food contact use of 23 phthalates and two other substances used as plasticizers, adhesives, defoaming agents, lubricants, resins, and slimicides.[7]

31. Companies and/or individuals who manufacture or market cosmetics have a legal responsibility and duty to ensure the safety of their own products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients, and the law also does not require cosmetic companies to share their safety information with the FDA.

32. The FDA has consistently advised manufacturers to use whatever testing is necessary to ensure the safety of products and ingredients, which may be substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information.[8]

33. Except for color additives and ingredients prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that (1) the ingredient and the finished cosmetic are safe under labeled or customary conditions of use, (2) the

[6] § 87 FR 31080.
[7] *Phthalates in Food Packages and Food Contact Applications*, U.S. Food and Drug Administration, https://www.fda.gov/food/food-ingredients-packaging/phthalates-food-packaging-and-food-contact-applications (last visited Oct. 27, 2022).
[8] *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, U.S. Food and Drug Administration, Mar., 3, 2005, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated (last visited Oct. 27, 2022).

product is properly labeled, and (3) the use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws the FDA enforces

34. Except for color additives and ingredients prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that (1) the ingredient and the finished cosmetic are safe under labeled or customary conditions of use, (2) the product is properly labeled, and (3) the use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws the FDA enforces.[9]

35. With respect to whether the product is properly labeled, Title 21 of the Code of Federal Regulations defines the establishment of warning statements related to cosmetic products. Section 740.1 states that "[t]he label of a cosmetic product ***shall*** bear a warning statement whenever necessary or appropriate to prevent a health hazard that ***may*** be associated with the product." (emphasis added). This warning directive directly correlates with the broad authority of manufacturers over their own cosmetic products to ensure that products are safe under labeled or customary conditions of use, properly labeled, and not adulterated or misbranded under FDA laws.

36. In short, under the current regulatory framework in the United States, it is incumbent upon the manufacturers of cosmetic products, and them alone, to assess the safety and efficacy of their products, and to warn consumers anytime a health hazard may be associated with their products. Here, a wealth of scientific information is available regarding long-term use of hair relaxers, straighteners and hair dyes as containing certain endocrine-disrupting chemicals, which should have alerted manufacturers of these products to the specific and dangerous harms associated with their products when used as intended, particularly in women of color.

[9] *Id.*

C. Endocrine-Disrupting Chemicals

37. The endocrine system is indispensable for life and influences nearly every cell, organ, and processes within the body.[10] The endocrine system regulates all biological processes in the body from conception through adulthood, including the development of the brain and nervous system, the growth and function of the reproductive system, as well as the metabolism and blood sugar levels.[11]

38. The endocrine system is a tightly regulated system made up of glands that produce and release precise amounts of hormones that bind to receptors located on specific target cells throughout the body.[12]

39. Hormones, such as estrogen, testosterone, progesterone, and androgen, are chemical signals that control or regulate critical biological processes.[13]

40. When a hormone binds to a target cell's receptor, the receptor carries out the hormone's instructions, the stimulus, and either switches on or switches off specific biological processes in cells, tissues, and organs.[14]

41. The precise functioning of the endocrine system is vital to maintain hormonal homeostasis, the body's natural hormonal production and degradation. A slight variation in hormone levels can lead to significant adverse-health effects, including reproductive impairment and infertility, cancer, cognitive deficits, immune disorders, and metabolic syndrome.[15]

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[10] *Endocrine System: The Endocrine System Includes The Thyroid, Adrenals, and the Pituitary Gland*, Science Direct, https://www.sciencedirect.com/topics/psychology/endocrine-system. (last visited Oct. 28, 2022).

[11] *Endocrine Disruption*, United States Environmental Protection Agency, Mar., 7, 2022, https://www.epa.gov/endocrine-disruption/what-endocrine-system. (last visited Oct. 28, 2022).

[12] *Id*.

[13] *Id.*

[14] *Id*.

[15] *Id*.; Michele La Merrill, et al., *Consensus on the Key Characteristics of Endocrine-Disrupting Chemicals as a Basis for Hazard Identification, Nature Reviews Endocrinol*, Nov. 12, 2019,

42. Endocrine disrupting chemicals ("EDCs") are chemicals, or chemical mixtures, that interfere with the normal activity of the endocrine system.

43. EDC's can act directly on hormone receptors as mimics or antagonists, or on proteins that control hormone delivery.[16]

44. EDCs disrupt the endocrine system and interfere with the body's hormonal homeostasis in various ways.

45. EDCs can cause the body to operate as if there were a proliferation of a hormone and thus over-respond to the stimulus or respond when it was not supposed to by mimicking a natural hormone.

46. EDCs can increase or decrease the levels of the body's hormones by affecting the production, degradation, and storage of hormones.

47. EDCs can block the hormone's stimulus through inducing epigenetic changes, modifications to DNA that regulate whether genes are turned on or off or altering the structure of target cells' receptors.[17]

48. EDCs are known to cause to numerous adverse human health outcomes including endometriosis, impaired sperm quality, abnormalities in reproductive organs, various cancers, altered nervous system and immune function, respiratory problems, metabolic issues, diabetes, obesity, cardiovascular problems, growth, neurological and learning disabilities.[18]

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https://www.nature.com/articles/s41574-019-0273-8 (last visited Oct. 28, 2022).

[16] Evanthia Diamanti-Kandarakis, et al., *Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement*, Endocrine Reviews, June 30, 2009, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726844/ (last visited Oct. 28, 2022).

[17] Luis Daniel Martínez-Razo, et al., *The impact of Di-(2-ethylhexyl) Phthalate and Mono(2-ethylhexyl) Phthalate in placental development, function, and pathophysiology*, Environment International, January 2021, https://www.sciencedirect.com/science/article/pii/S0160412020321838?via%3Dihub (last visited Oct. 28, 2022).

[18] *Endocrine Disrupting Chemicals (EDCs)*, Endocrine Society, Jan., 24, 2022, https://www.endocrine.org/patient-engagement/endocrine-

49. EDCs that mimic the effects of estrogen in the body may contribute to disease risk because exposure to estrogen, endogenously and exogenously, is associated with breast cancer, uterine cancer, ovarian and other types of hormone-sensitive cancers. A woman's lifetime risk of developing these hormone-sensitive cancers increases with greater duration and cumulative exposure.

50. Natural and synthetic EDCs are present in hair products under the guise of "fragrance" and "perfumes", and thus enter the body when these products are exogenously applied to the hair and scalp. Studies exploring this issue have thus far classified EDCs as estrogens, phthalates, and parabens.

51. Indeed, numerous studies spanning more than two decades have demonstrated the adverse impact EDCs including Di-2-ethylhexylphthalate have on the male and female reproductive systems such as inducing endometriosis, abnormal reproductive tract formation, decreased sperm counts and viability, pregnancy loss, and abnormal puberty onset.[19]

a. Phthalates

52. Phthalates are used in a variety of cosmetics and personal care products. Phthalates are chemical compounds developed in the last century that are used to make plastics more durable. These colorless, odorless, oily liquids also referred to as "plasticizers" based on their most common uses.

53. Phthalates also function as solvents and stabilizers in perfumes and other fragrance preparations. Cosmetics that may contain phthalates include nail polishes, hair sprays, aftershave

library/edcs#:~:text=EDCs%20can%20disrupt%20many%20different,%2C%20certain%20cancers%2C%20respiratory%20problems%2C (last visited Oct. 28, 2022).

[19] Hee-Su Kim, et al., *Hershberger Assays for Di-2-ethylhexyl Phthalate and Its Substitute Candidates*, Dev Reproduction, Mar., 22, 2018, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915764/ (last visited Oct. 28, 2022).

lotions, cleansers, and shampoos.

54. At all relevant times herein, phthalates were used in Defendants' products.

55. Phthalates are chemicals used to improve the stability and retention of fragrances and to help topical products stick to and penetrate skin and hair.[20]

56. Phthalates are known EDCs which interfere with natural hormone production and degradation and are detrimental to human health.[21]

57. Phthalates are commonly used by cosmetics and hair care product manufacturers to make fragrances and colors last longer, and to make hair more flexible after product is applied, among other uses.

58. Phthalates can be found in most products that have contact with plastics during producing, packaging, or delivering. Despite the short half-lives in tissues, chronic exposure to phthalates will adversely influence the endocrine system and functioning of multiple organs, which has negative long-term impacts on the success of pregnancy, child growth and development, and reproductive systems in both young children and adolescents. Several countries have established restrictions and regulations on some types of phthalates.[22]

59. Phthalates are a series of chemical substances, which are mainly used as plasticizers added to polyvinyl chloride ("PVC") plastics for softening effects. Phthalates can potentially disrupt the endocrine system.[23]

60. Defendants' products referenced herein contain phthalates, including Di-2-ethylhexylphthalate.

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[20] Olivia Koski & Sheila Hu, *Fighting Phthalates*, National Resources Defense Council, April 20, 2022, https://www.nrdc.org/stories/fighting-phthalates (last visited Oct. 28, 2022).
[21] Yufei Wang & Haifeng Qian, *Phthalates and Their Impacts on Human Health*, Healthcare (Basel) 9, 603, May 9, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8157593/ (last visited Oct. 28, 2022).
[22] *Id.*
[23] *Id.*

61. Under the authority of the Fair Packaging and Labeling Act ("FPLA"), the FDA requires an ingredient declaration on cosmetic products sold at the retail level to consumers. However, the regulations do not require the listing of the individual fragrance or flavor, or their specific ingredients meaning phthalates evade listing when combined with a fragrance. As a result, consumers, including Plaintiff, was not able to determine from the ingredient declaration on the label if phthalates were present in a fragrance used in the herein referenced hair products used by the Plaintiff and placed into the stream of commerce by Defendants.

62. Since 1999, the Centers for Disease Control ("CDC") have found phthalates in individuals studied for chemical exposure.[24]

b. Di-2-ethylhexylphthalate

63. Di-2-ethylhexylphthalate (DEHP)[25] is a highly toxic manufactured chemical[26] that is not found naturally in the environment.[27]

64. DEHP was first used in 1949 in United States and has been the most abundantly used phthalate derivative in the Twentieth century.[28]

65. DEHP does not covalently bind to its parent material. Non-covalent bonds are weak

[24] Biomarker Groups, National Report on Human Exposure to Environmental Chemicals, Center for Disease Control, https://www.cdc.gov/exposurereport/pdf/Biomarker_Groups_Infographic-508.pdf (last visited Oct. 28, 2022).
[25] Also known as Bis(2-ethylhexyl) phthalate.
[26] Sai Rowdhwal & Jiaxiang Chen, Toxic Effects of Di-2-ethylhexyl Phthalate: An Overview, Biomed Research International, Feb., 22, 2018 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5842715/#:~:text=DEHP%20is%20noncovalently%20bound%20to,and%20plastic%20waste%20disposal%20sites (last visited Oct. 28, 2022).
[27] *Toxicological Profile for Di(2-Ethylhexyl) Phthalate (DEHP)*, U.S. Dept of Health and Human Services, January 2022, https://www.atsdr.cdc.gov/ToxProfiles/tp9.pdf (DEHP is listed as hazardous pollutants under the Clean Air Act.; DEHP is on the Proposition 65 list because it can cause cancer and birth defects or other reproductive harm) (last visited Oct. 28, 2022).
[28] Pinar Erkekoglu & Belma Kocer-Gumusel, Environmental Effects of Endocrine-Disrupting Chemicals: A Special Focus on Phthalates and Bisphenol A, Environmental Health Risk, June 16, 2016, https://www.intechopen.com/chapters/50234 (last visited Oct. 28, 2022).

and, as a result, DEHP readily leaches into the environment increasing human exposure. [29]

66. Humans are exposed to DEHP through ingestion, inhalation, and dermal exposure for their lifetimes, including intrauterine life.[30]

67. The Agency for Toxic Substances and Disease Registry ("ATSDR") estimates that the range of daily human exposure to DEHP is 3–30 μg/kg/day.[31]

68. The no-observed-adverse-effect level for DEHP to humans is 4.8 mg/kg bodyweight/day and the tolerate daily intake (TDI) is 48 μg/kg bodyweight.[32]

69. When DEHP enters in the human body, it breaks down into specific metabolites. The toxicity of DEHP is mainly attributed to its unique metabolites which include the primary metabolite, mono-(2-ethylhexyl)phthalate (MEHP), and secondary metabolites, mono-(2-ethyl-5-hydroxyhexyl)phthalate (MEHHP), and mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP).[33]

70. DEHP and its metabolites are known to cause significant adverse-health effects

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[29] Katelyn H. Wong & Timur Durrani, *Exposures to Endocrine Disrupting Chemicals in Consumer Products – A Guide for Pediatricians*, Current Problems in Pediatric and Adolescent Health Care, Science Direct, May 2017, https://www.sciencedirect.com/science/article/pii/S1538544217300822?via%3Dihub (last visited Oct. 28, 2022).

[30] Schmidt, Juliane-Susanne, et al., *Effects of Di(2-ethylhexyl) Phthalate (DEHP) on Female Fertility and Adipogenesis in C3H/N Mice*, Environmental Health Perspective, May 15, 2012, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3440070/ (last visited Oct. 28, 2022).

[31] Hannon, Patrick et. al., *Daily Exposure to Di(2-ethylhexyl) Phthalate Alters Estous Cyclicity and Accelerates Primordial Follicle Recruitment Potentially Via Dysregulation of the Phosphatidylinositol 3-Kinase Signaling Pathway in Adult Mice*, Biology of Reproduction Volume 90, Issue 6, June 2014, 136, 1–11 https://academic.oup.com/biolreprod/article/90/6/136,%201-11/2514356 (last visited Oct. 28, 2022).

[32] Yufei Wang & Haifeng Qian, *Phthalates and Their Impacts on Human Health*, Healthcare (Basel) 9(5):603, May 18, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8157593/ (last visited Oct. 28, 2022).

[33] Saab, Yolande, et. al., *Risk Assessment of Phthalates and Their Metabolites in Hospitalized Patients: A Focus on Di- and Mono-(2-ethylhexyl) Phthalates Exposure from Intravenous Plastic Bags*. Toxics, 10(7), 357, https://pubmed.ncbi.nlm.nih.gov/35878262/ (last visited Oct. 28, 2022); Ishtaf Sheikh, et. at., *Endocrine disruption: In silico perspectives of interactions of di-(2-ethylhexyl)phthalate and its five major metabolites with progesterone receptor*. BMC Structural Biology Volume 16, Suppl 1, 16, Sept., 30, 2016, https://bmcstructbiol.biomedcentral.com/articles/10.1186/s12900-016-0066-4 (Other secondary metabolites include mono(2-ethyl-5-carboxypentyl)phthalate (5-cx-MEPP) and mono[2-(carboxymethyl)hexyl]phthalate (2-cx-MMHP)) (last visited Oct. 28, 2022).

including but not limited to, endometriosis, developmental abnormalities, reproductive dysfunction and infertility,[34] various cancers, and metabolic syndrome within the human population and their future children.[35]

71. Most of the available studies on the health effects of DEHP in laboratory animals used oral administration, with a few inhalation studies and only two dermal exposure studies identified.[36]

72. The results of the selected animal studies, along with limited human data, suggest potential associations between DEHP exposure and the following health outcomes:

a. **Reproductive effects.** Epidemiological studies suggest a potential association between DEHP exposure and decreased serum testosterone and altered sperm parameters in males. Available studies on fertility effects in humans do not indicate an association between DEHP exposure and infertility. In animals, the available oral and inhalation studies provide evidence that the male reproductive system, particularly the testes, is susceptible to DEHP toxicity. Evidence from animal studies indicates decreased male and female fertility at high oral doses.

b. **Developmental effects**. Epidemiological studies suggest a potential association between reduced AGD and testicular decent in male infants and prenatal DEHP exposure. In addition, human epidemiological studies provide mixed results for potential relationships between exposure to DEHP and preterm birth, early puberty,

[34] Richardson, Kadeem et. al., *Di(2-ethylhexyl) Phthalate (DEHP) Alters Proliferation and Uterine Gland Numbers in the Uterine of Adult Exposed Mice*, Reproductive Toxicology, 77, 70-79, https://pubmed.ncbi.nlm.nih.gov/29458081/ (last visited Oct. 28, 2022).
[35] Yufei Wang & Haifeng Qian, *Phthalates and Their Impacts on Human Health*, Healthcare (Basel) 9, 603, May 9, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8157593/ (last visited Oct. 28, 2022).
[36] *Chapter 2: Health Effects*, Toxicological profile for Di(2-ethylhexyl) phthalate (DEHP) (2001), https://www.atsdr.cdc.gov/ToxProfiles/tp9-c2.pdf (last visited Oct. 28, 2022).

and delayed mental and psychomotor development in children. Studies in animals indicate that altered glucose homeostasis and the development of the reproductive system following early life exposure is a particularly sensitive target of DEHP toxicity.

73. The global consumption of DEHP was estimated at 3.07 million tons (Global demand for plasticizers continues to rise). The estimated global market of phthalates in 2020 is expected to reach 10 billion USD and would still be widely used in plasticizers.[37]

74. Human epidemiological studies have shown a significant association between phthalates exposures and adverse reproductive outcomes in both women and men.[38]

75. Evidence found that DEHP was significantly related to insulin resistance and higher systolic blood pressure and the reproduction system problems, including earlier menopause, low birth weight, pregnancy loss, and preterm birth.[39]

76. When it comes to the impacts on children, epidemiological studies about phthalates toxicity focused on pregnancy outcomes, genital development, semen quality, precocious puberty, thyroid function, respiratory symptoms, and neurodevelopment.[40]

77. Since the turn of the century, restrictions on phthalates have been proposed in many Asian and western countries. In 2008, the U.S. Congress announced the Consumer Protection Safety Act (CPSA) that permanently banned the products, especially children's toys and childcare articles, containing DEHP, DBP, and BBP at levels >0.1% by weight.[41]

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[37] *Id.*
[38] *Id.*
[39] N.M. Grindler, et al., *Exposure to Phthalate, an Endocrine Disrupting Chemical, Alters the First Trimester Placental Methylome and Transcriptome in Women*, Scientific Reports Volume 8, April 17, 2018, https://doi.org/10.1038/s41598-018-24505-w (last visited Oct. 28, 2022).
[40] *Id.*
[41] Consumer Product Safety Improvement Act of 2008, H.R. 4040, 110th Cong. (2008), https://www.congress.gov/110/plaws/publ314/PLAW-110publ314.pdf (last visited Oct. 28, 2022).

D. Defendants' Marketing Efforts

78. The manufacture of any misbranded or adulterated drug is prohibited under federal law[42] and South Carolina state law.[43]

79. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[44]

80. The receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[45]

81. Among the ways a drug may be adulterated are:

> If it consists in whole or in part of any filthy, putrid, or decomposed substance; or . . . whereby it may have been rendered injurious to health; . . . .[46]

82. A drug is misbranded:

> (a) "If its labeling is false or misleading in any particular."[47]
>
> (b) If the labeling does not contain, among other things, "the proportion of each active ingredient[.]"[48]
>
> (d) "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[49]

83. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[50]

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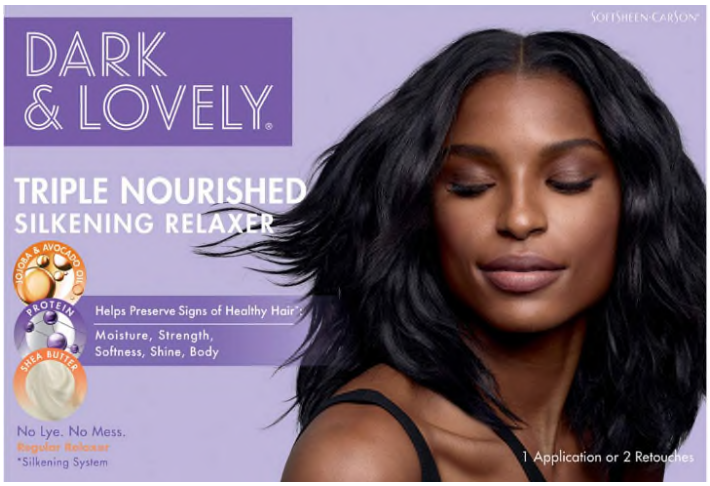
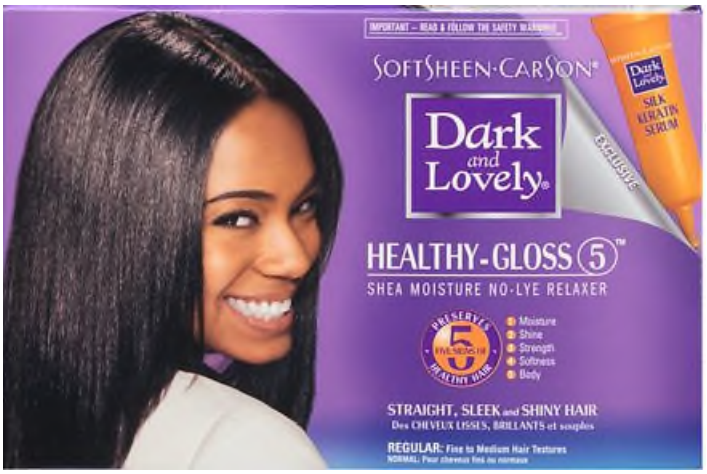
[42] 21 U.S.C. §331(g).
[43] *See* S.C. Code Ann. § 39-23-80(2).
[44] 21 U.S.C. §331(a).
[45] 21 U.S.C. §331(c).
[46] 21 U.S.C. §351(a)(2)(B).
[47] 21 U.S.C. §352(a)(1).
[48] 21 U.S.C. §352(e)(1)(A)(ii).
[49] 21 U.S.C. §352(j).
[50] 21 C.F.R. §§201.6. "The labeling of a drug may be misleading by reason (among other reasons) of: … (2) Failure to reveal the proportion of, or other fact with respect to, an ingredient present in such drug, when such proportion or other fact is material in the light of the representation that such ingredient is present in such drug." 21 C.F.R. §201.10(2).

84. Because Defendants did not disclose that EDCs may be present in the Toxic Hair-Straightener and/or Relaxers purchased and used by Plaintiff, the Toxic Hair-Straightener and/or Relaxers are adulterated and misbranded. There is no "no safe level of EDC" exposure, so it is unsuitable for human application while these EDCs remain as ingredients in hair straighteners and/or relaxers.

85. Defendants wrongfully advertised and sold the Toxic Hair-Straightener and/or Relaxers without any labeling to indicate to consumers that these products may contain EDCs and may cause endometrial (uterine) cancer. The following images provide an example:





COUNT ONE – SRICT LIABILITY (Failure to Warn)
(Against Defendant Manufacturers)

86. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

87. At all pertinent times, Defendants were manufacturing, marketing, testing, promoting, selling, and/or distributing the Product in the regular course of business.

88. At all pertinent times, Plaintiff used the Product on her scalp area, which is a reasonably foreseeable use.

89. At all pertinent times, Defendants in this action knew or should have known that the use phthalates and other EDC's in hair products significantly increases the risk of cancer, based upon scientific knowledge dating back for decades.

90. At all pertinent times, including the time of sale and consumption, the Product, when put to the aforementioned reasonably foreseeable use, were in an unreasonably dangerous and defective condition because they failed to contain adequate and proper warnings and/or instructions regarding the increased risk of cancer associated with the use of the Defendant's hair products. Defendants themselves failed to properly and adequately warn and instruct Plaintiff as to the risks and benefits of the Product given her need for this information.

91. Had Plaintiff received a warning that the use of the Product would significantly increase her risk of developing endometrial (uterine) cancer, she would not have used them.

92. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of the Product, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

93. The development of endometrial (uterine) cancer by Plaintiff was the direct and proximate result of the unreasonably dangerous and defective condition of the Product that existed

at the time of sale and consumption (*i.e.*, when the Product left the Defendant manufacturer's control), including the lack of warnings. Plaintiff suffered injuries and damages including, but not limited to physical and mental pain and suffering, and medical expenses.

94. Defendants' Product was defective because they failed to contain warnings and/or instructions and breached express warranties and/or failed to conform to express factual representations upon which Plaintiff justifiably relied in electing to use the Products. The defect or defects made the Product unreasonably dangerous to persons, such as Plaintiff, who could reasonably be expected to use and rely upon such Product. As a result, the defect or defects were a producing cause of Plaintiff's injuries and damages.

95. Defendants' Product failed to contain, and continue to this day not to contain, adequate warnings and/or instructions regarding the increased risk of cancer, including but not limited to breast cancer, uterine cancer, and ovarian cancer with the use of their products. Defendants continue to market, advertise, and expressly represent to the general public that it is safe for women to use their products. Defendants continue with these marketing and advertising campaigns despite having scientific knowledge dating back to 2011 that establishes that their products increase the risk of cancer—specifically, breast cancer—in women.

96. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT TWO - SRICT LIABILITY (Design Defect)
(Against Defendant Manufacturers)

97. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

98. Defendants engaged in the design, development, manufacture, marketing, sale, and distribution of the Product in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

99. Defendants caused the Product to enter the stream of commerce and to be sold through various retailers where Plaintiff purchased the Products.

100. The Products were expected to, and did, reach consumers, including Plaintiff, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.

101. Plaintiff used the Product in a manner normally intended, recommended, promoted, and marketed by Defendants.

102. The Product failed to perform safely when used by Plaintiff in a reasonably foreseeable manner, specifically increasing her of developing endometrial (uterine) cancer.

103. The propensity for endocrine disrupting chemicals, such as phthalates, to trigger cancerous growths in premenopausal women, including but not limited to the uterus and/or ovaries, thereby substantially increasing the risk of endometrial (uterine) (or other) cancer(s), renders the Product unreasonably dangerous when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

104. Importantly, the Product is an inessential cosmetic product that do not treat or cure any serious disease. Further, safer alternatives, including fragrance-free products, have been readily available for decades.

105. Defendants have known, or should have known, that the Product is unreasonably dangerous but have continued to design, manufacture, sell, distribute, market, promote, and supply the Product so as to maximize sales and profits at the expense of public health and safety in

conscious disregard of the foreseeable harm to the consuming public, including Plaintiff.

106. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT THREE - SRICT LIABILITY (Manufacturing Defect)
(Against Defendant Manufacturers)

107. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

108. At all relevant times. Defendants engaged in the design, development, manufacture, marketing, sale, and distribution of the Product in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

109. Defendants caused the Product to enter the stream of commerce and to be sold through various retailers, where Plaintiff purchased the Product.

110. The Product was expected to, and did, reach consumers, including Plaintiff, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.

111. Plaintiff used the Product in a manner normally intended, recommended, promoted, and marketed by Defendants.

112. The Product failed to perform safely when used by Plaintiff in a reasonably foreseeable manner, specifically increasing her risk of developing uterine (endometrial) cancer.

113. The propensity of other endocrine disrupting chemicals, such as phthalates, to trigger cancerous growths in premenopausal women, including but not limited to the uterus and/or ovaries, thereby substantially increasing the risk of endometrial (uterine) (and other) cancer(s),

renders the Product unreasonably dangerous when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

114. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT FOUR – NEGLIGENCE / GROSS NEGLIGENCE
(Against Defendant Manufacturers)

115. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

116. Defendants' owed a duty of reasonable care to Plaintiff and other reasonably foreseeable consumers to not only ensure that their Product was safe for intended use but that the product labeling adequately warned of any and all risks associated with use of their products.

117. Defendants also owed a duty of reasonable care to Plaintiff and other reasonably foreseeable consumers to not market, design, manufacture, produce, supply, inspect, test, sell, and/or distribute unsafe and dangerous products that they knew or should have known through the exercise of reasonable diligence were unsafe and dangerous due to the presence of EDCs, such as phthalates.

118. Defendants breached this duty of care owed to Plaintiff by failing to ensure their Product was safe for use, as intended, as well as placing into the stream of commerce an unsafe and dangerous/toxic product.

119. Consequently, it was reasonably foreseeable that Plaintiff—as a reasonable, foreseeable consumer—would purchase and use Defendants' hair straightener and/or relaxer products and suffer injury from such use due to the presence of toxic and dangerous EDCs, such

as phthalates.

120. Plaintiff's injuries are also directly caused by Defendants' breach of the duty of reasonable care owed to Plaintiff, as but for Defendants' failure to appropriately warn of the inherent dangers associated with use of their Product, Plaintiff would not have purchased and/or used it and would not have suffered serious injury, including uterine (endometrial) cancer.

121. The Defendants' negligence and extreme carelessness includes but is not limited to their marketing, designing, manufacturing, producing, supplying, inspecting, testing, selling, and/or distributing the Product in one or more of the following respects:

a. In failing to warn Plaintiff of the hazards associated with the use of the Product;

b. In failing to properly test their products to determine adequacy and effectiveness or safety measures, if any, prior to releasing the Product for consumer use;

c. In failing to properly test their products to determine the increased risk of uterine (endometrial) cancer during the normal and/or intended use of the Product;

d. In failing to inform ultimate users, such as Plaintiff as to the safe and proper methods of handling and using the Product;

e. In failing to remove the Products from the market when Defendants knew or should have known the Product was defective;

f. In failing to instruct the ultimate users, such as Plaintiff, as to the methods for reducing the type of exposure to the Product which caused increased risk of cancer, including, but not limited to, uterine (endometrial) cancer;

g. In failing to inform the public in general and Plaintiff in particular of the known dangers of using the Product;

h. In failing to advise users how to prevent or reduce exposure that caused increased risk for cancer, including, but not limited to, uterine (endometrial) cancer;

i. In marketing and labeling the Product as safe for all uses despite knowledge to the contrary; and

j. In failing to act like a reasonably prudent company under similar circumstances. Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by Plaintiff.

122. At all pertinent times, Defendants knew or should have known that the Product was unreasonably dangerous and defective when put to its reasonably anticipated use.

123. Defendants' acts and/or omissions constitute gross negligence because they constitute a total lack of care and an extreme departure from what a reasonably careful company would do in the same situation to prevent foreseeable harm to Plaintiff.

124. Defendants acted and/or failed to act willfully, and with conscious and reckless disregard for the rights and interests of Plaintiff, and their acts and omissions had a great probability of causing significant harm and in fact resulted in such harm to Plaintiff.

125. Plaintiff was injured as a direct and proximate result of negligence and/or gross negligence as described herein.

126. Defendants' negligence and/or gross negligence were a substantial factor in causing and/or contributing to Plaintiff's harms.

127. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT FIVE – NEGLIGENCE (Failure to Warn)
(Against Defendant Manufacturers)

128. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

129. At all relevant times. Defendants engaged in the design, development, manufacture, marketing, sale, and distribution of the Product in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

130. Defendants knew, or by the exercise of reasonable care, should have known that use of their Product was dangerous, harmful, and injurious when used by Plaintiff in a reasonably foreseeable manner.

131. Defendants knew, or by the exercise of reasonable care, should have known that ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of their Product, and that Product was likely to increase the risks of cancerous growths in premenopausal women, including but not limited to the uterus and/or ovaries, thereby substantially increasing the risk of endometrial (uterine) (and other) cancers, when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

132. Defendants owed a duty to all reasonably foreseeable consumers, including Plaintiff, to disclose the risks associated with the use of their Product.

133. Defendants breached their duty of care by failing to use reasonable care in providing adequate warnings on their Product, including that Product was likely to increase the risks of cancerous growths in premenopausal women, including but not limited to the uterus and/or ovaries, thereby substantially increasing the risk of endometrial (uterine) (and other) cancers, when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

134. The failure of Defendants to adequately warn about their defective Product, and their efforts to misleadingly advertise through conventional avenues, created a danger of injuries described herein that were reasonably foreseeable at the time of design and/or manufacture and distribution.

135. At all relevant times, Defendants could have provided adequate warnings and instructions to prevent the harms and injuries set forth herein, such as providing full and accurate

information about the products in advertising.

136. A reasonable company under the same or similar circumstances could have and would have warned and instructed of the dangers.

137. Plaintiff was injured as a direct and proximate result of Defendants' failure to warn and instruct because she would not have used the Product had she received adequate warnings and instructions that the Product could increase the risks of cancerous growths in premenopausal women, including but not limited to the uterus and/or ovaries, thereby substantially increasing the risk of endometrial (uterine) (and other) cancer(s), when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

138. Defendants' lack of adequate and sufficient warnings and instructions, and their inadequate and misleading advertising, was a substantial contributing factor in causing harm to Plaintiff.

139. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT SIX – NEGLIGENCE (Design Defect and/or Manufacturing Defect)
(Against Defendant Manufacturers)

140. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

141. At all relevant times, Defendants engaged in the design, development, manufacture, marketing, sale, and distribution of the Product in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

142. Defendants caused the Product to enter the stream of commerce and to be sold

through various retailers, where Plaintiff purchased the Product.

143. The Product was expected to, and did, reach consumers, including Plaintiff, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.

144. Plaintiff used the Product in a manner normally intended, recommended, promoted, and marketed by Defendants.

145. The Product failed to perform safely when used by Plaintiff in a reasonably foreseeable manner, specifically increasing her risk of developing endometrial (uterine) cancer.

146. The propensity of endocrine disrupting chemicals, including phthalates, to trigger cancerous growths in premenopausal women, including but not limited to the uterus and/or ovaries, thereby substantially increasing the risk of endometrial (uterine) (and other) cancer(s), renders the Products unreasonably dangerous when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

147. Importantly, the Product is an inessential cosmetic product that do not treat or cure any serious disease. Further, safer alternatives, including fragrance-free products, have been readily available for decades.

148. Defendants knew, or by the exercise of reasonably care should have known, that the Product is unreasonably dangerous but have continued to design, manufacture, sell, distribute, market, promote, and supply the Product so as to maximize sales and profits at the expense of public health and safety in conscious disregard of the foreseeable harm to the consuming public, including Plaintiff.

149. Defendants owed a duty to all reasonably foreseeable users to design a safe product.

150. Defendants breached their duty by failing to use reasonable care in the design

and/or manufacturing of their Product because the Product was unreasonably dangerous in that they increase the risks of cancerous growths in premenopausal women, including but not limited to the uterus and/or ovaries, thereby substantially increasing the risk of endometrial (uterine) (and other) cancer(s), renders the Product unreasonably dangerous when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

151. Defendants also breached their duty by failing to use reasonable care by failing to use cost-effective, reasonably feasible alternative deigns in the design and/or manufacturing of their Product.

152. A reasonable company under the same or similar circumstances would have designed a safer product.

153. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT SEVEN – NEGLIGENCE (Negligent Misrepresentation/Omission)
(Against Defendant Manufacturers)

154. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

155. Through their labeling and advertising, Defendants made representations to the Plaintiff concerning the active and inactive ingredients in their Toxic Hair-Straightener and/or Relaxers, including Dark & Lovely.

156. Defendants have a duty to provide accurate information to consumers with respect to the ingredients identified in their Toxic Hair-Straightener and/or Relaxers as detailed above.

157. Defendants failed to fulfill its duty to accurately disclose in its labeling and

advertising that the Toxic Hair-Straightener and/or Relaxers contained EDCs.

158. Defendants acted with carelessness and/or negligence in ascertaining the truth of the marketing statements associated with the Product.

159. Additionally, Defendants have a duty to not make false representations with respect to their Toxic Hair-Straightener and/or Relaxers.

160. Defendants failed to fulfill its duty when it made false representations regarding the quality and safety of the Toxic Hair-Straightener and/or Relaxers as detailed above.

161. Such failures to disclose on the part of Defendants amount to negligent omission, and the representations regarding the quality and safety of the product amount to negligent misrepresentation.

162. Plaintiff reasonably relied upon such representations and omissions to her detriment.

163. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT EIGHT - VIOLATION OF THE SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT (S.C. Code Ann §§ 39-5-10 through 39-5-180)
(Against Defendant Manufacturers)

164. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

165. The South Carolina Unfair Trade Practices Act ("SCUTPA") makes unlawful:

a. Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. S.C. Code Ann. § 39-5-20.

166. Defendants have violated and continue to violate SCUPTA by, among other things,

(1) misrepresenting that their Product was safe when in fact it is unsafe because it contains EDCs, (2) failing to disclose to consumers in their labeling or otherwise that their Product contained toxic and dangerous EDCs, and (3) continuing to market, advertise, and sell the Product that is adulterated with EDCs.

167. Defendants knew, or through the exercise of reasonable care should have known, that its Product was adulterated with EDCs. Defendants' unfair conduct, as described herein, is intentional, and Defendants intend for consumers to rely on its unfair and misleading practices, including with respect to Defendants' decision to continue to sell its Product containing EDCs.

168. Defendants' conduct, as described herein, occurred in the course of trade or commerce.

169. Defendants' conduct, as described herein, violates SCUPTA because it (1) offends public policy; (2) is immoral, unethical, oppressive, or unscrupulous; and (3) causes substantial injury to consumers.

170. Defendants' conduct offends the public policy of South Carolina in that it violates a standard of conduct contained in an existing statute or common law doctrine that typically applies to a situation. Specifically, among other things, it is unfair and misleading to represent to consumers that a product is safe and contains the ingredients identified on the label when in fact that product is unsafe because it contains a cancer-causing chemical not identified on the label.

171. Defendants' conduct, as described herein, has caused and continues to cause substantial injury to Plaintiff.

172. Additionally, Defendants made deceptive statements and omissions regarding the Product. Defendants represented that the Product was safe when it is not because it is adulterated with EDCs. And, Defendants did not disclose that the Product contains EDCs when it does.

173. Defendants' deceptive statements and omissions are material because they concern ingredients, contaminants, and safety—which are among the types of information that Plaintiff would be expected to rely upon in making purchasing decisions.

174. Defendants' deceptive statements and omissions have the capacity to, and did, Plaintiff by inducing her to purchase the Product.

175. Defendants' intended for Plaintiff to rely on its deceptive statements and omissions by purchasing the Product.

176. Defendants made its deceptive statements and omissions in the course of conduct involving trade or commerce.

177. Plaintiff has been injured as a direct and proximate result of Defendants' deceptive conduct in violation of SCUPTA. Plaintiff paid for and frequently used the Product as a result of Defendants' deceptive statements and omissions.

178. Through its deceptive practices, Defendants have improperly obtained and retained money from Plaintiff.

179. The injury caused by Defendants' conduct is not outweighed by any countervailing benefits to consumers, including Plaintiff, or to competition.

180. The injury caused by Defendants' conduct could not reasonably have been avoided by Plaintiff because she did not know and could not have known that the Product was adulterated with EDCs, particularly given that EDCs is not listed as an ingredient on the Product's label.

181. As a direct and proximate result of Defendants' violations of the State of South Carolina's consumer protection laws, Plaintiff sustained the following damages: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and

impairment of quality of life, past and future.

COUNT NINE – FRAUD
(Against Defendant Manufacturers)

182. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

183. Defendants, who engaged in the development, manufacture, marketing, sale, and distribution of cosmetic and personal care products, including the Product, owed a duty to provide accurate and complete information regarding said products.

184. Defendants fraudulently misrepresented the use of the Product as safe and effective, specifically:

a. Defendants' Dark & Lovely Product is intentionally labeled as "Triple Nourished Silkening Relaxer" that "helps preserve signs of healthy hair;"

b. Dark & Lovely is marketed with "[n]ew Fiber Strength post-treatment, infused with proteins, [to] help[] preserve the internal strength of the hair;" and

c. Defendant Softsheen-Carson LLC's website states that Dark & Lovely uses "Shea Butter, Jojoba and Avocado Oils" that they claim "deliver conditioning care for softness and body;"

185. Defendants knew that these misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive, and deceitful when they were made.

186. Defendants made the misrepresentations and/or omissions for the purpose of deceiving and defrauding consumers, including Plaintiff, with the intention of having them act and rely on such misrepresentations and/or omissions.

187. Plaintiff relied, with reasonable justification, on the misrepresentations by Defendants, which induced her to purchase and use the Product on a regular basis for decades.

188. Defendants profited, significantly, from their unethical and illegal conduct that fraudulently induced Plaintiff, and millions of other consumers, to purchase a dangerous and

defective product.

189. Defendants' actions, and Plaintiff's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

190. As a foreseeable, direct, and proximate result of the aforementioned fraudulent misrepresentations by Defendants, Plaintiff sustained the following damages: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT TEN – FRAUDULENT CONCEALMENT
(Against Defendant Manufacturers)

191. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

192. Defendants owed consumers, including Plaintiff, a duty to fully and accurately disclose all material facts regarding the Product, not to conceal material defects related thereto, not to place these defective products into the stream of commerce and to fully and accurately label product packaging. To the contrary, Defendants explicitly and/or implicitly represented that the Product was safe and effective.

193. Defendants actively and intentionally concealed and/or suppressed material facts, in whole or in part, to induce consumers, including Plaintiff, to purchase and use the Product and did so at her expense. Specifically, Defendants have been aware of the positive association between DEHP used in their products and an increased risk of cancer demonstrated by epidemiology studies since at least 2015 that exposure to the phthalates in their products enhance invasive and proliferative activities of endometrial cells.

194. Recent studies have established a statistically significant correlation between

Defendants' Product and endometrial (uterine) cancer.

195. Defendants made the misrepresentations and/or omissions for the purpose of deceiving and defrauding Plaintiff and with the intention of having her act and rely on such misrepresentations and/or omissions.

196. Defendants knew that their concealments, misrepresentations, and/or omissions were material, and that they were false, incomplete, misleading, deceptive, and deceitful when they were made. Alternatively, Defendants concealed information and/or made the representations with such reckless disregard for the truth that knowledge of the falsity can be imputed to them.

197. Defendants profited, significantly, from their unethical and illegal conduct that caused Plaintiff to purchase and habitually use a dangerous and defective product.

198. Defendants' actions and representations, and Plaintiff's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

199. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT ELEVEN – BREACH OF EXPRESS WARRANTY
(Against Defendant Manufacturers)

200. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

201. As detailed above, Defendants, through their direct-to-consumer marketing, written literature, packaging and labeling, and written and media advertisement, expressly warranted that the Product was safe and fit for the purposes intended, that it was of merchantable quality, and that it did not pose dangerous health risks.

202. The Product did not conform to these express representations because they cause serious injury when used in the manner directed by Defendants in the form of cancer, including, but not limited to, uterine (endometrial) cancer.

203. Plaintiff read and relied on these express warranties provided by Defendants in the packaging and written advertisements.

204. Defendants breached its express warranties because the Product is defective and not reasonably safe for its intended use.

205. Defendants knew or should have known that the Product did not conform to their express warranties and representations and that, in fact, the Product is not safe and poses serious health risks, such as uterine (endometrial) cancer, because it contains EDCs.

206. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT TWELVE – BREACH OF IMPLIED WARRANTY
(Against Defendant Manufacturers)

207. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

208. At the time Defendants manufactured, marketed, labeled, promoted, distributed, and/or sold the Product, Defendants knew of the uses for which the Product was intended and impliedly warranted the Product to be of merchantable quality and safe for such use.

209. Defendants breached their implied warranties of the Product sold to Plaintiff because it was not fit for their common, ordinary, and intended uses.

210. Specifically, because the Product contains EDCs, it was not of the same quality as

those generally acceptable in the trade and was not fit for the ordinary purposes for which such Hair-Straightener and/or Relaxers are used.

211. Plaintiff used the Product in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

212. The Product was not altered by Plaintiff.

213. Plaintiff was a foreseeable user of the Product.

214. Plaintiff used the Product in the manner intended.

215. Defendants impliedly warranted that the Product was merchantable, fit, and safe for ordinary use.

216. Defendants further impliedly warranted that the Product was fit for the particular purposes for which it was intended and sold.

217. Contrary to these implied warranties, Defendants' Product was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the particular purpose for which it was sold.

218. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT THIRTEEN – NEGLIGENT FAILURE TO RECALL
(Against Defendant Manufacturers)

219. At all relevant times, Defendants designed, developed, managed, operated, inspected, tested (or not), marketed, advertised, promoted, disseminated, made publicly available, and/or benefited from the Product and, therefore, owed a duty of reasonable care to avoid causing harm to those who used the Product, such as Plaintiff.

220. Defendants knew or should have known through the exercise of reasonable care the risks to consumers posed by the inherent dangerousness of the Product.

221. Defendants knew or, by the exercise of reasonable care, should have known use of the Product was harmful and had the potential to increase the risks of cancerous growths in premenopausal women, including but not limited to the uterus and/or ovaries, thereby substantially increasing the risk of endometrial (uterine) (and other) cancer(s), renders the Product unreasonably dangerous when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

222. Defendants owed a duty to the users of the Product, including Plaintiff, to exercise reasonable care in conducting their business to properly and reasonably design, research, develop, manufacture, produce, process, assemble, inspect, supply, distribute, deliver, broker, market, warn, maintain, repair, modify, recall, retrofit, engineer, test, recommend, advertise, and/or make available the Product.

223. Defendants also owed a continuing duty to Plaintiff to remove, recall, or retrofit the unsafe and/or defective platforms across the United States (including in Plaintiff's state).

224. As discussed, Defendants knew or reasonably should have known that the Product was dangerous and not safe for use.

225. Defendants knew or, in the exercise of reasonable and ordinary care, should have known that the Product was defective and unsafe for Plaintiff, who is a person likely to use the Product for the purpose and in the manner for which the Product was intended to be used and for purposes reasonably foreseeable to Defendants.

226. However, at all times, Defendants negligently breached said duties and unreasonably and negligently allowed the Product to be used by Plaintiff without proper recall or

retrofit or warning.

227. Defendants have also not made any reasonable effort to remove and/or retrofit the serious safety risk posed by the Product to consumers.

228. In failing to properly recall and/or retrofit the Product, or even warn of the serious safety risks the platforms pose to consumers and the public, Defendants have failed to act as a reasonable manufacturer, designer, or distributer would under the same or similar circumstances and failed to exercise reasonable care.

229. Plaintiff was injured as a direct and proximate result of the negligent conduct as described herein.

230. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

COUNT FOURTEEN - MEDICAL MONITORING
(Against Defendant Manufacturers)

231. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

232. Defendants provided misinformation about the presence of EDCs in their Hair-Straighteners and/or Relaxers which are harmful to women's' health as described herein and, as a result, Defendants succeeded in persuading large segments of the relevant consumer market to purchase and use Defendants' Hair Straightening and/or Relaxing Products, like Dark & Lovely, despite the presence of significant dangers, as set forth herein.

233. Defendants had a pre-marketing, post-manufacturing, and continuing duty to warn, which arose when Defendants knew, or with reasonable care should have known, that Defendants'

Product was injurious or fatal.

234. Defendants omitted, suppressed, and/or concealed material facts concerning the dangers and risks associated with the use of the Product, including but not limited to the risks of disease, cancer, death, and other health problems associated with the use of the Product. Defendants failed to disclose that the Product contained toxic chemicals, including EDCs, and/or purposely downplayed and/or understated the serious nature of the risks associated with the use of the Product. Instead, Defendants' encouraged the use of their Product despite knowledge of the dangerous side effects that hair straighteners and/or relaxers present to the consuming population, including Ms. Davis and her subsequent diagnosis of endometrial (uterine) cancer.

235. Defendants falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed material facts regarding the ingredients contained within the Product and the risk posed by those ingredients to the public.

236. Had Plaintiff known that the Product contained the dangerous ingredients described herein and/or that those ingredients could cause serious life-threatening injuries, such as endometrial (uterine) cancer, she would not have used the Product.

237. Defendants knew or should have known, and would have known had appropriate testing been done, that the use of the Product caused Ms. Davis serious and potentially life-threatening endometrial (uterine) cancer and other health-related issues, such as uterine fibroids.

238. Defendants' actions as set forth herein constitute knowing omission, suppression, or concealment of material facts made with the intent that others will rely upon such concealment, suppression, or omission, in connection with the marketing of the Product.

239. Defendants' actions as described herein evidence lack of good faith, honesty in fact, and observance of fair dealing so as to constitute unconscionable commercial practices.

240. Plaintiff has suffered serious injury— endometrial (uterine) cancer requiring a total hysterectomy and a bilateral salpingo-oophorectomy—for which Defendants are liable to Plaintiff.

241. As a proximate result of using Defendants' Toxic Hair-Straighteners and/or Relaxers, Plaintiff has been significantly exposed to toxic chemicals and thereby has suffered an increased risk of disease and/or injury—not including the injury she is currently suffering from due to use of Defendants' products (*i.e.*, endometrial (uterine) cancer)—making the periodic examination of Plaintiff both reasonable and medically necessary.

242. There currently exists a means to detect the onset of disease and/or injury, as well as the other adverse health problems caused by the use of the Product, at an early stage, such that subsequent treatment would have a higher chance of success at prolonging life and reducing suffering than would exist without such monitoring and treatment.

243. The prescribed monitoring regime is different from that normally recommended in the absence of the exposure to this drug and is reasonably necessary according to contemporary medical and scientific principles.

244. The increased susceptibility to injuries and irreparable threat to the health of Plaintiff resulting from her exposure to this hazardous substance can only be mitigated or redressed by the Defendant's providing and/or compensating Plaintiff for the costs of medical monitoring for cancer and cancer-related conditions that are necessary as a result of using the Product.

245. As a result of Defendants' marketing of its Hair Straighteners and/or Relaxers and Plaintiff's use thereof, Plaintiff is entitled to appropriate medical monitoring funded by Defendants, including but not limited to, testing, medical care, and preventative screening.

246. The foregoing wrongful, tortious, and negligent acts, omissions, and conduct by Defendants constitute actionable negligence.

247. Defendants' negligent, tortuous, and wrongful acts are a proximate cause of Plaintiff's suffering an increased risk of further developing serious injury and disease, which she will continue to suffer. Plaintiff has been exposed to a hazardous product and suffers a significantly increased risk of contracting serious injury and even death—apart from the serious injury she is currently suffering from due to use of Defendants' products. This increased risk makes periodic diagnostic and medical examinations reasonable and necessary.

248. Medical monitoring is particularly appropriate and, indeed, imperative, with respect to this action as:

a. Defendants' Hair Straighteners and/or Relaxers have been found to cause cancer, including breast, uterine, ovarian, and other hormone-driven cancers and diseases, such as Plaintiff's.

b. It is reasonably believed that the injuries and damage caused by Defendants' Hair Straighteners and/or Relaxers may be latent, asymptomatic, chronic, and/or undiscovered in the absence of medical monitoring for these cancers and other health conditions.

249. Early detection and diagnosis of these diseases is clinically invaluable since it can prevent, reduce, and/or significantly delay resulting discomfort, suffering, and/or death, particularly because these conditions can be often asymptomatic absent proper testing.

250. Easily administered, cost-effective monitoring and testing procedures exist which make the early detection and treatment of such injuries or disease possible and beneficial. Early diagnosis of diseases and conditions will allow prompt and effective treatment which will reduce the risk of morbidity and mortality which these patients would suffer if treatment were delayed until their condition became overly symptomatic.

251. Appropriate tests include non-invasive, readily administrable initial tests and procedures.

252. The increased susceptibility to injuries and irreparable threat to the health of

Plaintiff resulting from her exposure to the Product can only be mitigated or addressed by appropriate medical testing.

253. By reason of the foregoing, Defendants are liable to Plaintiff for the costs of periodic medical monitoring. Plaintiff demands judgment against Defendants for medical monitoring damages to diagnose the platforms induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT FIFTEEN – NEGLIGENCE *PER SE*

254. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

255. Under South Carolina law, "negligence per se simply means the jury need not decide if the defendant acted as a reasonable man in the circumstances. The statute fixes the standard of conduct required of the defendant, leaving the jury merely to decide whether the defendant breached the statute. If he did, his failure to take due care is established as a matter of law." *Rayfield v. S.C. Dept. of Corr.*, 297 S.C. 95, 103 (Ct. App. 1988).

256. Notwithstanding there being no private right of action under the Food, Drug, & Cosmetic Act ("FDCA"), the FDCA provides the definition for the standard of care owed to Plaintiff by Defendants.

257. As part of their duty to exercise reasonable care, Defendants were obligated to follow the regulations enacted and promulgated under the FDCA to protect the safety of consumers, such as Plaintiff.

258. Defendants actions and/or omissions related to the Product violated (and continue to violate) 21 U.S.C. § 331(a), which prohibits "[t]he introduction or delivery for introduction into

interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

259. Specifically, the label for Defendants Toxic Hair Straighteners and/or Relaxers is misbranded within the meaning of 21 U.S.C. § 362(a) because it was false and misleading and failed to give adequate warnings and directions for use by consumers who purchase and use the Product.

260. Defendants each had a statutory duty under 21 U.S.C. § 362 not to misbrand their Hair Straighteners and/or Relaxers; however, Defendants violated this duty that was owed to Plaintiff.

261. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers, like Plaintiff, thus making Defendants liable to Plaintiff.

262. Defendants' negligence per se directly and proximately caused injury to Plaintiff as described more fully herein.

263. Plaintiff sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions: (1) economic losses including medical care and lost earnings; and (2) noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment, and impairment of quality of life, past and future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as to each and every count, including:

A. Awarding compensatory damages in excess of $75,000, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial of this action;

B. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings, and other economic damages in an amount to be determined at trial of this action;

C. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

D. Prejudgment interest;

E. Postjudgment interest;

F. Awarding Plaintiff's reasonable attorneys' fees;

G. Awarding Plaintiff the costs of these proceedings; and

H. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated this 20th day of January 2023.

Respectfully submitted,

/s/Chelsea L. Monroe

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